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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,179	03/27/2002	Nobuaki Yatsuka	0230-0174P	3270

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,179	YATSUKA ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *November 3, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1, 8, and 13 have been amended. Claim 17 has been newly added. Claim 1 and 8-17 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 8, 10, 12, and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 13 are drawn to method for preventing/treating (claim 8) or preventing (claim 13) various dermatological disorders mediated by the production of excessive sebum. However, the claims require administration to subject presenting said disorder. It is not clear how a disorder is to be prevented in a subject already afflicted with said disorder. The claims are thus rendered vague and indefinite.

Claims 10 and 12 are drawn to the treatment of "increased dandruff" or "increased body odor." The term "increased" in the claims is a relative term which renders the claim indefinite. The term "increased" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

Claims 1 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 11-310588; JP 10-372864; and JP 10-273895. The references disclose the compounds recited in the instant claims. These compounds are not identified as sebum production inhibitors. However, there is no limitation in the instant claims that differentiates them from the compound *per se*. The claims are thus anticipated.

Claims 1, 8-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by SCOTT (EP 295092).

SCOTT discloses compositions comprising hyaluronic acid (HA) fragments of 7 to 20-25 monosaccharide units. See examples 1, 3, 10, and 11. The precise chemical structure of the HA fragments is not explicitly identified. However, the fragments are prepared by the same method, enzymatic depolymerization by hyaluronidase, so must have the same structure. See page 3, lines 1-41. The reference further teaches a method of administering the composition for the enhancement of hair (re)growth. See abstract. The other recited disorders are inherently prevented by application.

Claim Rejections - 35 USC § 103

Claims 1 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over UNILEVER (EP 295092).

UNILEVER teaches as set forth above. The reference does not exemplify application to human subjects. However, such application is specifically suggested. See page 3, last line. It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the disclosed compositions to human skin for the treatment of alopecia. The artisan would reasonably expect success because the reference teaches that the composition has the utility for (re)growth of hair and suggests its use in humans.

The reference does not teach the treatment of (increased) body odor associated with aging. However, the reference teaches application of the disclosed compositions for the rejuvenation of aged, wrinkled skin. See page 2, lines 43-45. This suggests an overlap in the patient population with that recited in claim 12. Therefore, in using the composition as prescribed in the art, application to aged skin, other dermatological disorders associated with aging would also be accomplished.

Claims 1, 8, 10, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over UNILEVER (EP 295092) in view of SHISEIDO (JP 11-236319). Because the SHISEIDO reference is in Japanese, the examiner is relying in part on the English abstract from Patent Abstracts of Japan.

UNILEVER teaches as set forth above. The reference does not teach the treatment of dandruff.

SHISEIDO teaches the use of HA for the treatment of dandruff. See abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the UNILEVER composition for the treatment of dandruff.

UNILEVER had taught that the composition comprising HA fragments had utility for the treatment of scalp/skin disorders. Because SHISEIDO had taught that HA had utility in the treatment of dandruff, in the absence of unexpected results, one of ordinary skill would reasonably expect success in using HA fragment for the treatment of dandruff.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 19 of U.S. Patent No. 6,613,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claim 1 discloses a genus of compounds having substantial overlap with the instant claims. Furthermore, claims 3-8 each recite a sub-genus encompassed by the instant claims. Therefore, the instant claims are obvious over the claims of '897. It is noted that the products of claims 1 and 17 are recited as "sebum production inhibitors," but there is no limitation recited that would differentiate them from the compounds *per se*.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0626. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
February 6, 2004